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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,113	05/30/2001	C. Alexander Turner JR.	LEX-0182-USA	6538

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,113	TURNER ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1, 3-16 are still at issue and are present for examination.

Applicants' amendments and arguments filed on 5-19-03, paper No.8, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 4-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants have not asserted a proper utility for the claimed isolated polynucleotides encoding the amino acid sequences with of SEQ ID NO:2, 4, 6, 10 and 12. Applicants have characterized the polynucleotides as those that encode novel human mitochondrial proteins which share structural motifs typical of mitochondrial solute carriers, RNA splicing proteins, uncoupling proteins and mitochondrial carrier proteins. However, applicants do not first of all provide the information as to which specific polypeptide has which specific function. Applicants have simply provided a group of polypeptides and broadly assigned the functional characteristics to the group of the polypeptides and claim polynucleotides which encode them. Second, even if it is concluded for example, that all claimed polynucleotides encode a solute carrier, applicants do not denote as to which specific solute is carried by which specific protein (i.e., which specific SEQ ID NO) in the case of mitochondrial solute carrier or if it is concluded that all claimed polynucleotides encode a RNA splicing protein, which specific RNA is spliced by them or which specific polypeptide from among the four SEQ IDs has such an activity. Thus

the functional characteristics or the ultimate utility of the polypeptides encoded by the claimed polynucleotides is not specific and substantiated. Therefore, other than the polynucleotide sequence, SEQ ID NO:1, 3, 5, 9, 11 and the amino acid sequence that is encoded by the polynucleotide as set forth in SEQ ID NO:2, 4, 6, 10 and 12 respectively, the specification provides little functional characterization of the claimed polynucleotides. The specification also lists a general use for the polypeptides encoded by the polynucleotides, however, there is no information that links the use of the polynucleotides with SEQ ID NO: 1, 3, 5, 9, 11. Thus the asserted utility of the claimed polynucleotides is not substantial or specific. Further, while the specification discloses that SEQ ID NO: 1, 3, 5, 9, 11 and its fragments will be used to generate probes, and the encoded polypeptides will be used for making antibodies, that is not a utility specific to the claimed polynucleotide or polypeptide sequence.

Claims 1, 3, 4-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants are referred to the revised interim guidelines concerning compliance with utility requirement of U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants have traversed the above rejection arguing at great length that they do not agree with the Examiner's position that the claimed polynucleotides lack utility. Applicants argue that they have clearly described the presently claimed sequences as mitochondrial proteins that have a role in RNA splicing. Applicants also provide a post dated reference which discloses a 100% identity (to which SEQ ID NO?) at protein level over the entire length of the claimed sequence and is annotated by third party as human mRNA for mitochondrial RNA splicing protein 3/4 (HMRS3/4 gene), wherein the

publication reports that the said gene restores mitochondrial function in yeast and therefore there can be no question that those skilled in the art would clearly believe that applicants' sequence is a mitochondrial protein involved in RNA splicing. Examiner respectfully disagrees with such a conclusion. This is because, applicants do not make it clear as to with which SEQ ID NO is the 100% match and/or which specific polypeptide encoded by the claimed polynucleotide has which specific function. Applicants are claiming a bunch of polynucleotides encoding a bunch of polypeptides which are grossly assigned a bunch of functions without providing the specifics. With such ambiguous information, one skilled in the art would be unable to use the polypeptides encoded by the claimed polynucleotides.

Applicants argue that the Federal Circuit in *Juicy Whip Inc. v. Orange Bang, Inc.* has stated that the threshold of utility is not high and that an invention is useful under section 101 if it is capable of providing some identifiable benefit. Applicants further cite *Brooktree Corp. v. Advanced Micro Devices, Inc.* to indicate that the Federal Circuit has stated that a claimed device must be totally incapable of achieving a useful result to lack utility under 35 USC § 101. Applicants cite *Cross v. Iizuka* in support of the argument that any utility for a claimed invention is sufficient to satisfy the requirements of 35 USC § 101 and indicate that the Federal Circuit has confirmed that anything under the sun made by man is patentable in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*

The Examiner acknowledges the numerous cases cited by applicants wherein issues regarding to 35 USC § 101, utility were argued. Examiner does note that in *Juicy Whip Inc. v. Orange Bang, Inc.,* the issue of utility was with regard to a juice dispenser, *in Brooktree Corp. v. Advanced Micro Devices, Inc.,* the issue of utility was regarding a digital to analog conversion circuitry, and in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.,* the issue of utility was regarding a business method. However it is beyond the scope of this Office action at

this time during the prosecution of this case to respond to each one without knowing the claims involved and the prosecution history of each of the cases cited.

Applicants argue that in *In re Brana*, the Federal Circuit admonished the PTO for confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. Applicants recite part of the decision and emphasize that the Federal Circuit referred to utility within the context of 35 USC § 101 and usefulness within the context of 35 USC § 112, first paragraph. Applicants specifically emphasize a statement of *In re Brana* which reads "pharmaceutical inventions, necessarily includes the expectation of further research and development". In applicant's opinion, the need for experimentation does not render the claimed invention unpatentable and they state that a considerable amount of experimentation is permissible so long as such experimentation is routinely practiced in the art. Applicants further argue that according to *In re Wands*, a patent need not to disclose what is well known in the art.

While it is agreed that FDA approval is not a requirement for finding a compound patentably useful and that routine experimentation does not render an invention unpatentable, it is noted that in the instant case, the utility rejection was not applied to the claimed invention because it failed to comply with government requirements to market the invention for human consumption or because some routine experimentation is required to practice the claimed invention. Instead, the utility rejection was applied due to the lack of information as to its biological function as already discussed. The specification fails to disclose information in regard to the specific biological activity/function of each of the protein encoded by the claimed polynucleotides. As known in the art and admitted by applicants in the specification, mitochondrial proteins have varied but specific functions. Applicants list four polypeptides encoded by four polynucleotides, calling them all mitochondrial proteins and assigning a number of activities in general starting from solute carrier to uncoupling protein activity.

Furthermore, SEQ ID NO:4 appears to be a fragment of 193 amino acids of SEQ ID NO:2. However, the specific activities of the two polypeptides are not clear. Since, the specific activity or the function of each of the polypeptide encoded by the claimed polynucleotides are not clear or unknown, further research is required to identify or reasonably confirm a "real world" context of use (Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966)). Applicant's argument that a third party validated the utility in a post-dated reference overcomes the instant utility is highly misplaced. In view of the large amount of information unknown in regard to the claimed invention, it is not reasonable for one of skill in the art to conclude that the additional research required to practice the claimed invention is merely routine. In regard to *In re Wands*, while it is agreed that one need not disclose what is well known in the art, it is noted that neither the specification nor the state of the art describes or provides any information regarding the specific biological function of each of the polypeptide encoded by the claimed polynucleotides other than to indicate that the encoded polypeptides of the instant invention are mitochondrial proteins. As previously explained this, by itself, is insufficient to provide the skilled artisan with the knowledge of how to use the claimed polynucleotides. Since information regarding all the encoded polypeptides which would enable one of skill in the art to practice the claimed invention is not known in the art, it is the specification which must provide the necessary information to enable the skilled artisan to practice the claimed invention.

Next, applicants argue that an additional utility of the claimed polynucleotides is in the DNA chip. Applicants argue that due to the widespread utility of gene chips using public domain gene information, there can be no doubt that the claimed polynucleotides can be used in DNA chip applications. Applicants further argue that the claimed polynucleotides and their sequences provide a specific marker of the human genome, and that such specific markers are targets for discovering drugs that are associated with human disease. It is the applicant's opinion that one of skill in the art would instantly recognize that the present polynucleotides would be

ideal candidates for assessing gene expression using DNA chips. In addition, applicants assert that DNA chips have utility as evidenced by hundreds of issued patents and recite examples of such patents. Applicants argue that the present polynucleotides have a specific utility in DNA chip applications and that compositions comprising the claimed polynucleotides enhance the utility of DNA chips. Applicant's arguments in regard to utility of the claimed polynucleotides in DNA chips have not been found persuasive. While it is agreed that the use of polynucleotides in DNA chips (microarrays) is widespread and that the claimed polynucleotides can be attached to DNA chips, for the claimed polynucleotides to be specifically useful in such application, one would require some knowledge or guidance as to the specific biological role of the polypeptides encoded by said polynucleotides, to effectively use the information gathered in tracking the expression patterns of such polynucleotides. The reduction or increase in expression of a polynucleotide is meaningless unless one can link changes in expression with some biological function. For example, if one were to use the claimed polynucleotides in assays which would lead to the discovery of drugs of a specific condition, such as an assay which uses a DNA chip to evaluate expression patterns upon exposure to a test compound, one need to know which diseases and/or biological functions are associated with the expression of such polynucleotides. Otherwise, one of skill in the art would have to carry out further experimentation to determine which are the conditions (i.e. diseases) and/or biological functions associated with the claimed polynucleotides. Applicant's asserted utility of the claimed polynucleotides as specific markers which are targets for discovering drugs associated with human disease is not a specific and substantial utility since the specification is silent in regard to (1) the conditions and/or biological functions which are associated with the expression of each of the claimed polynucleotides, (2) whether increase or decrease in expression of each of the claimed polynucleotide correlates with a specific disease, and (3) which levels of increase or decrease in expression of the claimed polynucleotides are indicative of the presence or absence of a disease. This is analogous to the

examples provided by MPEP § 2107.01 in regard to what constitutes carrying out further research to identify or reasonably confirm a "real world" context of use since basic research is required to determine the properties or the mechanisms in which the claimed product is involved. The Examiner acknowledges the hundreds of issued patents in regard to DNA chips however it is noted that the instant claims are not drawn to methods of use of DNA chips or to DNA chips (microarrays) but rather to specific polynucleotides. Furthermore, the asserted use of the claimed polynucleotides in DNA chips is not specific since as Applicants have stated, many other polynucleotides including those in the public domain can and are used in DNA chips. In regard to the argument that the claimed polynucleotides can be used as specific markers of the human genome, it is noted that there is no disclosure in the specification as to how is the claimed invention a specific marker of the human genome. This situation is analogous to the examples provided in MPEP § 2107.01 in regard to what constitute a non-specific utility since, as stated MPEP § 2107.01 "a specific utility is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to a broad class of inventions". Therefore, in view of the lack of information as to the biological function and/or condition associated with the expression of the claimed polynucleotides or how the claimed invention is a specific marker of the human genome, it is unclear how one of skill in the art can reasonably conclude that the asserted use of the claimed polynucleotides in DNA chips is a specific and substantial utility.

Applicants argue that further evidence of "real world" substantial utility, is the fact that there is an entire industry established based on the use of polynucleotides (i.e. gene sequences) or fragments thereof in a gene chip format. Applicants further recite the many companies involved in the manufacture of DNA chips (i.e. gene chips or microarrays) and companies which at some point or another concentrated on the use of polynucleotides or fragments. Since large amounts of money were paid by large pharmaceutical companies to purchase companies which deal with DNA chips, polynucleotides and fragments, applicants argue that it is clear that the use

of polynucleotides (i.e. gene sequences) or fragments is a "real world" substantial, widespread and well-established utility. Furthermore, applicants argue that one of skill in the art can recognize the utility of genomic data in general, and specifically human genomic data, (e.g.Venter et al. and Jasny et al.) to support their argument that the usefulness of human genomic data, including the claimed polynucleotides, is substantial and credible, since it is worth billions of dollars and has resulted in the creation of many companies, and well-established, since the utility of human genomic information has been clearly understood for many years. While it is agreed that (1) there is an industry based on the use of polynucleotides and fragments, (2) there are many billions of dollars invested in companies which use DNA chips and related technologies, (3) billions of dollars have been spent in the generation of human genomic data, and (4) the utility of human genomic data has been understood for many years, applicant's arguments have not been found persuasive for the following reasons. First, it is noted that it is the patentable utility of the specific polynucleotides claimed in the instant application and not the general utility of DNA chips, polynucleotides or fragments, which is being determined and discussed. The Examiner is not disputing the patentable utility of DNA chips as a collection of polynucleotides linked to a solid support but rather the patentable utility of specific polynucleotides encoding an alleged protein whose function is ambiguous in the specification. Furthermore, the Examiner is not disputing that one of skill in the art can see the potential usefulness of information coming out of the human genome project. It is known in the art that this information is valuable to the extent that it provides a starting point for scientists to further investigate the biological significance of the genetic information collected and possibly discover how to treat many conditions and diseases. In fact, while the potential usefulness of human genomic data was enormous, the lack of an immediate use for human genomic data was the primary reason why it was the federal government and not a private entity who first provided funding for the Human Genome Project. While it is agreed that the disclosure of an additional

human polynucleotide provides more information in regard to the human genome, as indicated previously, in the absence of any additional information in regard to its biological function, the isolation of the human polynucleotides of the instant application is only useful as a starting point for researchers to further investigate its biological significance, therefore the utility of the instant polynucleotides, as clearly stated in MPEP § 2107.01 is not a "real world" substantial utility.

Next, applicants argue that although only one credible assertion of utility is needed to meet the requirements of 35 USC § 101, the claimed polynucleotides have specific utility in determining the genomic structure of the corresponding human chromosome as described in the specification. It is applicant's opinion that the claimed polynucleotides provide exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the polypeptide of the instant application and that this specificity is useful because one can use the claimed polynucleotides as markers to map a specific locus of the human genome.

While it is agreed that the claimed polynucleotides can in fact be used in detecting the particular locus (i.e. position in the chromosome at which the gene resides) of the human genome where the gene encoding the polypeptide is located, such use is not considered specific for the following reasons. As known in the art, any human polynucleotide which encodes a protein can be used to detect the particular locus of the corresponding gene, therefore any human polynucleotide which encodes a protein can be used to determine the specific chromosome which contains that locus. In addition, while one could argue that the claimed polynucleotides can be used as markers to isolate the particular chromosome which contains the locus of the gene encoding the polypeptide of SEQ ID NO: 2, 4, 6, or 12, since that chromosome will contain many other genes, any polynucleotide which is complementary to any of those other genes will also serve as a marker for that particular chromosome. In regard to the use of the claimed polynucleotides in producing a genetic map of high resolution, which can then be used to identify specific genes involved in disease, it is noted that this use is not specific since many

other polynucleotides which encode proteins as indicated above can be used in a similar way. In addition, it is noted that there is no disclosure in the specification as to any diseases, conditions or biological changes associated with modifications in the structure (i.e. mutations) of the gene encoding the polypeptide of SEQ ID NO: 2, 4, 6, or 12, which would lead one of skill in the art to use the claimed polynucleotides as probes to detect mutations in that specific locus (i.e. specific markers). It is interesting to note that the reference cited by the applicants concludes that the authors did not detect any mutations in the hMRS3/4 rendering it unlikely to be the disease gene (see page 84, column 2).

Applicants argue that since only a minor portion of the genome contains exons (i.e. DNA which encodes amino acids), the claimed polynucleotides provide biologically validated empirical data that specifically define that portion of the genomic locus that actually contains an exon. In addition, Applicants argue that the claimed polynucleotides define how the exons are spliced to produce an active transcript. Applicants further direct the Board's attention to an article by Venter et al., pages 1317-1321, which discusses the significance of expressed sequence information in the structural analysis of genomic data. Applicants conclude that since their polynucleotides define biologically validated empirical data, the present claims meet the requirements of 35 USC 101.

While it is agreed that (1) only a small portion of the genome contains exons and (2) ESTs (expressed sequence tags) as disclosed by Venter et al. are of great significance in the analysis of genomic data specifically in the area of gene prediction and function annotation, it is unclear how the claimed polynucleotides provide biologically validated data for the following reasons. As known in the art and also discussed in Venter et al. pages 1317-1321, automated gene annotation (i.e. computer-based annotation of function based on sequence homology) uses among other things, ESTs (partial sequences of expressed genes) as one of the tools to identify and annotate genes and their corresponding cDNAs (i.e. transcripts which encode proteins and

lack introns). The information provided by ESTs along with protein similarity data is used to assemble cDNAs. Since applicants have disclosed the use of sequence homology to determine the alleged function (KIP) of the protein encoded by the claimed polynucleotides, such polynucleotides (cDNA since they encode the polypeptide of SEQ ID NO: 2, 4, 6 or 12) may have been assembled with the use of ESTs. As such, there is no assurance that the assembled cDNA encoding the polypeptide of SEQ ID NO: 2, 4, 6, or 12 is indeed an actual transcript of a gene since it is known in the art that computer-based assembly of genes and their transcripts (cDNA) is not perfect and may lead to wrong splicing of genes. In fact, Venter et al., page 1320, second column, last paragraph, indicates that their annotation algorithm (Otto), in the absence of the corresponding experimental evidence, has in some cases incorrectly predicted gene splicing and the wrong transcript has been predicted. Since applicants provide no experimental evidence to corroborate that the claimed polynucleotides are indeed the actual transcripts of a gene, one cannot reasonably conclude that the claimed polynucleotides provide biologically validated data.

Applicants indicate that while they are aware of the new utility guidelines set forth by the USPTO, the current rules and regulations are the patent laws set forth in 35 USC and the rules set forth in 37 CFR but not the Manual of Patent Examination Procedure (MPEP) set forth by the USPTO. Furthermore, Applicants argue that it is the job of the judiciary and not the USPTO to interpret these laws and rules. Applicants argue that there are no recent changes in either 35 USC § 101 or in the interpretation of 35 USC § 101 by the Supreme Court or the Federal Circuit which support the new utility guidelines set forth by the USPTO and submit examples of US patents, which, according to applicants, do not comply with the new utility guidelines. While applicants admit that each application is examined on its own merits, applicants conclude that holding them to a different standard of utility is a clear violation of due process due to the similarity in subject matter between the claimed invention and the inventions in the cited US patents. Applicants are reminded that the Examiner must examine a patent application according

to the guidelines set forth by the USPTO as well as the MPEP, since the Examiner has no authority to disregard such guidelines or to apply his/her own interpretation of patent law in the examination of the application. Furthermore, as set forth in the guidelines and the MPEP, the guidelines were promulgated by the PTO in accordance with all applicable case law and thus are believed to be consistent therewith. While the Examiner acknowledges the cited US patents, each application is examined on its own merits according to the current guidelines of examination as set forth by the USPTO and a discussion on the utility of any polynucleotide claimed in such patents would require a detailed review of the record of each individual case, which is again beyond the scope of this Office action at this time during the prosecution of the instant application. Finally, applicants are further reminded that the Examiner has no authority to comment in regard to the legality of the new utility guidelines or the MPEP as set forth by the USPTO.

Applicants have also traversed the above rejection under 35 U.S.C. 112, Ist paragraph as being non-enabled, since one skilled n the art would not know how to use the invention as the invention is not supported by a specific, substantial and credible utility or a well-established utility. Applicants submit that as claims 1 and 3 have been shown by them to have specific, substantial and credible utility, the instant rejection cannot stand. Examiner respectfully disagrees with such an argument, since Examiner has maintained and provided reasons as to why claims continue to lack specific, substantial and credible utility. Therefore, rejection of claims as non-enabled under 35 U.S.C. 112, Ist paragraph is maintained.

Claims 1, 3 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA

molecules with either SEQ ID NO:1, 3, 5, 9 or 11 or DNA encoding a polypeptide with SEQ ID NO:2, 4, 6, 10 and 12. The specification does not contain any disclosure of the specific function of each of DNA sequences SEQ ID NO: 1, 3, 5, 9 or 11. The genus of DNAs that comprise these above DNA molecules is a variable genus with the potentiality of encoding proteins whose functions are not clearly described. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only the structure of the polynucleotides which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants have traversed reciting from several court cases. Applicants argue that the federal circuit court in *Vas-Cath. v. Mahurkar* (19USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention and that it is important to note the use of the terms "reasonable clarity to those skilled in the art". Examiner has no arguments against the above court decision, and has in fact used the same measure to determine the written description. Examiner reiterates here that applicants have not disclosed the function of each and every polypeptide encoded by the claimed polynucleotides. Applicants are claiming a bunch of polynucleotides by providing a bunch of functions to them without providing the specifics as to which specific polynucleotide encodes a polypeptide that has a specific function. Applicants' labeling of all the encoded

polypeptides as "mitochondirial proteins" encompassing a number of diverse activities and concluding that they have satisfied written description is highly misplaced.

Applicants go on to recite a number of other court cases and the court rulings that were handed down in those cases. However none of those situations appear to exist in the instant case and therefore cannot be used for comparison.

As discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure **of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics**, sufficient to show the applicant was in possession of the claimed genus. In the instant case the claimed genera of polynucleotides encoding polypeptides lack functional correlations. As such, neither the description of the structure of polynucleotides SEQ ID NO:1, 3, 5, 11 encoding polypeptides with SEQ ID NO:2, 4, 6, and 12 nor the combined functions as "mitochondrial proteins" without providing specific function of each of those "mitochondrial proteins" is not sufficient to satisfy written description requirements.

Conclusion

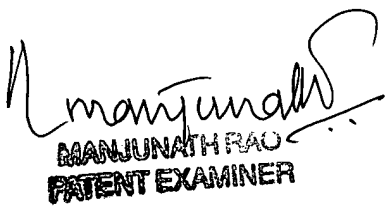
None of the claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao
August 1, 2003